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APPLICATION FOR LETTERS PATENT FOR:

METHOD OF MANUFACTURING A LINER SOCK FOR USE BETWEEN A LIMB PROSTHESIS AND A LIMB LINER

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RELATED APPLICATIONS

This application is a Continuation-In-Part of copending application serial No. 09/632,187, entitled Device For Improving The Fit Between A Limb Prosthesis And A Limb Liner, which was filed on August 03, 2000.

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

In general, the present invention relates to methods of manufacturing liner socks that are used to improve the fit of a limb prosthesis with the human body. More particularly, the present invention relates to the manufacture of liner socks that are worn between a limb liner and a limb prosthesis.

2. PRIOR ART STATEMENT

Many people who have amputated limbs or partially amputated limbs rely upon prosthetic limbs to better live a more normal life. When a person is fitted for a limb prosthesis, a limb liner is typically placed over the

portion of the limb stump that remains on the body. A limb liner is an elastomeric device that is pulled over the limb stump. The liner conforms to the shape of the limb stump and creates a strong frictional attachment to the skin of the limb stump. In many instances, a metal locking pin extends from the tip of the limb liner. The locking pin is used to engage a prosthetic limb, when a prosthetic limb is mated with the limb liner. As such, the limb liner acts as the anchor for retaining the limb prosthesis onto the limb stump.

When a limb prosthesis, that utilizes a limb liner, is manufactured, a cast is taken of the limb liner while the limb liner worn in place on the limb stump. The cast is used to produce a socket. The socket is then attached to the limb prosthesis. The socket of the limb prosthesis is the portion of the limb prosthesis that mates with the limb liner and conforms to the shape of the stump. In this manner, the limb prosthesis manufactured will theoretically mate perfectly with the limb liner and the limb prosthesis will be properly fitted onto the limb stump.

Amputees commonly retain their prosthetic limbs for many years. However, during this time, the amputee may

gain weight, lose weight, lose muscle mass in the stump or otherwise undergo physiological changes in their bodies that effect the size and contour of the limb stump. As the stump changes in size and/or contour, the configuration of the limb liner also changes. As a result, the configuration of the limb liner is no longer matched by configuration of the socket in the prosthetic limb. This causes gaps to occur between the limb liner and the limb prosthesis when the limb prosthesis is worn. The gaps can cause the limb prosthesis to feel loose. Furthermore, the gaps can cause physical discomfort by causing chafing against the limb stump.

In the prior art, fabric-based liner socks have been used to compensate for any inconsistencies between the configuration of the limb liner and the configuration of the limb prosthesis. Prior art liner socks are basically knitted or woven socks that are worn over the limb liner. The liner sock is compressed between the limb liner and the limb prosthesis when the limb prosthesis is worn. The liner sock becomes highly compressed at points of contact between the limb liner and the limb prosthesis and less compressed in areas of gaps. Accordingly, the liner sock helps to fill the gaps between the limb liner and the

limb prosthesis and makes for a better fit.

A problem associated with prior art liner socks is that as they are unevenly compressed between the limb liner and the limb prosthesis, uneven pressure points are exerted against the limb liner and the underlying skin. The uneven pressure points may cause discomfort or more serious problems such as chafing or blistering.

A need therefore exists for a new type of liner sock that can compensate for irregularities between a limb liner and a limb prosthesis without causing pressure points against the limb stump. This need is met by the present invention as described and claimed below.

SUMMARY OF THE INVENTION

The present invention is a method of manufacturing a liner sock device for placement between a limb liner and a limb prosthesis. The liner sock contains an elastomeric material, such as a tri-block copolymer gel. The elastomeric material is preferably a gel that uniformly distributes stresses between the limb liner and the limb prosthesis when the liner sock is worn between the limb liner and the limb prosthesis. The entire liner sock is fabricated from elastomeric material that is bonded to

either one or two fabric sock elements. Regardless to the construction, the liner sock has a first end and a second end. The second end of the liner sock is open to allow the liner sock to be pulled over a limb liner. The first end of the liner sock defines an aperture that enables a locking pin from the limb liner to protrude through the liner sock and engage the prosthetic limb.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, reference is made to the following description of exemplary embodiments thereof, considered in conjunction with the accompanying drawings, in which:

FIG. 1 is a perspective view of a liner sock device in accordance with the present invention. The liner sock is shown in conjunction with a limb stump, a limb liner and a limb prosthesis.

FIG. 2 is a cross-sectional view of the liner sock device shown in Fig. 1.

FIG. 3 is a cross-sectional view of a second exemplary embodiment of the present invention liner sock;

FIG. 4 is a cross-sectional view of a third exemplary embodiment of the present invention liner sock;

FIG. 5A illustrates the first set of method steps used to manufacture the liner sock device of Fig. 2;

FIG. 5B illustrates the second set of method steps used to manufacture the liner sock device of Fig. 2;

FIG. 5C illustrates the third set of method steps used to manufacture the liner sock device of Fig. 2;

FIG. 6 is a method flow schematic illustrating an exemplary method of manufacture for the liner sock device of Fig. 4.

DETAILED DESCRIPTION OF THE INVENTION

Although the present invention device can be used in conjunction with either an arm prosthesis or a leg

prosthesis, an application with a leg prosthesis is shown and described merely by way of example.

Referring to Fig. 1, an exemplary embodiment of the present invention device 10 is shown in conjunction with a traditional limb liner 12 and a segment of a limb prosthesis 14. The limb liner 12 has an elastomeric body 15 that can be pulled over the limb stump 16 of an amputee. Once in place over the limb stump 16, the elastomeric body 15 of the limb liner 12 conforms to the configuration of the limb stump 16. A metal locking pin 18 extends forwardly from the apex of the limb liner 12. It is the metal locking pin 18 that is physically engaged by the limb prosthesis 14.

The limb prosthesis 14 contains a socket 20 that is shaped to mate with the limb liner 12 when the limb liner 12 is present over the limb stump 16.

The present invention liner sock 10 is a generally tubular structure having a first end 22 and a second end 24. The first end 22 of the liner sock 10 defines a small aperture 26. The aperture 26 is reinforced by at least one reinforcement patch 28 which will later be explained. The second end 24 of the liner sock 10 is fully open. The second end 24 of the liner sock 10 is sized to fit over

the limb liner 12 so that the liner sock 10 can be pulled over the limb liner 12. The aperture 26 at the first end 22 of the liner sock 10 is sized to enable the locking pin 18 of the limb liner 12 to pass therethrough.

Referring to Fig. 2, in conjunction with Fig. 1, it can be seen that the illustrated liner sock 10 has a laminated construction. The inner most layer 30 of the liner sock 10 is fabric, wherein fabric refers to either woven or knitted threads. The inner layer of fabric 30 extends from the first end 22 of the liner sock 10 to the second end 24 of the liner sock 10. The outer most layer 32 of the liner sock 10 is also fabric. The outer most layer of fabric 32 also extends the full length of the liner sock 10 from the first end 22 of the liner sock 10 to the second end 24 of the liner sock 10. The inner layer of fabric 30 and the outer layer of fabric 32 are coupled together at the second end 24 of the liner sock 10 with a joining stitch, adhesive or some other coupling means.

An elastomeric material 34 is interposed between the inner layer of fabric 30 and the outer layer of fabric 32. The elastomeric material 34 is bonded to both the outer layer of fabric 32 and the inner layer of fabric

30. Referring now solely to Fig. 2, it can be seen that the elastomeric material 34 extends from the first end 22 of the liner sock 22 a predetermined distance D toward the second end 24 of the liner sock 10. The predetermined distance D can be any length. For example, the elastomeric material 34 may just coat the closed end of the liner sock. However, in a preferred embodiment, the elastomeric material 34 extends between the middle of the liner sock 10 and the full length of the liner sock 10. By way of example, the shown embodiment shows the elastomeric material 34 extending approximately 3/4 the total length of the liner sock 10.

Although the elastomeric material 34 can be any material with elastomeric properties, such as foam rubber, silicon impregnated foam, and the like. The preferred embodiment uses a tri-block copolymer mixed with an oil to form an elastomeric gel. Suitable tri-block copolymers would include poly(styrene-ethylene-butylene-styrene and poly(styrene-ethylene-propylene-styrene).

The elastomeric material 34 spreads when it is compressed. As a result, when the liner sock 10 is compressed between the limb liner 12 (Fig. 1) and the

limb prosthesis 14 (Fig.1) the elastomeric material 34 inside the liner sock 10 spreads from points of high compression into points of low compression. The result is a much more even pressure across the entire limb liner/ limb prosthesis interface. Additionally, the elastomeric material 34 spreads to fill any voids at the limb liner/ limb prosthesis interface. Accordingly, the elastomeric material 34 in the liner sock 10 compensates for any irregularities that exist between the limb liner 12 (Fig. 1) and the limb prosthesis 14 (Fig. 1). The limb prosthesis therefore fits better and can be worn in a more conformable manner despite any physiological changes that may occur in the limb stump over time.

Referring to Fig. 3, a second embodiment of a liner sock 50 is shown. In this embodiment, a first fabric sock element 52 is provided. The fabric sock element 52 is then coated with an elastomeric material 54 in the same manner as the embodiment of Fig. 2. However, in the shown embodiment of Fig. 3, the elastomeric material 54 is allowed to cure without the application of a second sock element. As a result, the liner sock 50 has one surface that is fabric and another surface that is comprised of the elastomeric material. The liner sock 50 can be worn

either with the fabric contacting the limb liner and the elastomeric material contacting the limb prosthesis or vise versa.

An aperture 56 is disposed through the first end of the liner sock 50. The aperture 56 is sized so that a metal locking pin of a limb liner can pass through the aperture 56. An optional reinforcement patch 58 can be attached to the fabric sock element 52 in the area surrounding the aperture 56. The benefits of the reinforcement patch are later explained.

Referring to Fig. 4, a third embodiment of a liner sock 60 is shown. In this embodiment, an first fabric sock element 62 is provided. The fabric sock element 62 is then coated with an elastomeric material 64 on both its internal surface and its external surface. As a result, the liner sock 60 has a laminated construction wherein both elastomeric material 64 is present on both sides of a fabric sock element 62. The elastomeric material 64 on one side of the fabric sock element 62 will contact the limb liner, while the elastomeric material 64 on the opposite side of the fabric sock element 62 will contact the limb prosthesis.

An aperture 66 is disposed through the first end of

the liner sock 60. The aperture 66 is sized so that a metal locking pin of a limb liner can pass through the aperture 66.

Referring to Fig. 5A, the first three steps used in the manufacturing the liner sock of Fig. 2 are illustrated. The first step used to manufacture the liner sock is to manufacture an initial interior sock element 30 in a traditional manner. As such, this would be typically done on a programmable knitting machine. The interior sock element 30 has a first end 82 that is closed and a second end 84 that is open, as is traditional for socks. In Step 2, the interior sock element 30 is placed on a dipping blank 85 that retains the interior sock element in a preferred shape for dipping. In Step 3, the interior sock element 30, while supported by the dipping blank 85, is then dipped in a volume of molten elastomeric material 86. The molten elastomeric material can be any non-thermoset elastic material. However, the preferred elastomeric material is a triblock copolymer mixed with a plasticizing oil. The depth of the dip, the number of dips and the temperature of the molten material determines the length and the thickness of the elastomeric layer 34 coating the

interior sock element 30. Accordingly, the thickness of the elastomeric layer 34 can be selectively controlled in the process.

After a desired length and thickness of elastomeric layer 34 is obtained, the elastomeric layer 34 is allowed to cool or otherwise cure. Referring to Fig. 5C, it can be seen by Step 4 that an exterior sock element 32 is then produced in a traditional manner. The exterior sock element 32 has a closed first end 87, an open second end 88 and is sized to receive the interior sock element 32 coated with the elastomeric layer 34. The external sock element 32 is then pulled over both the elastomeric layer 34 and the internal sock element 30 to produce an unattached assembly. As is indicated by Step 5, the unattached assembly 89 is then heated, whereby the outermost parts of the elastomeric layer 34 melts and bonds to the external sock element 32, thereby creating an attached assembly.

In Step 6, the attached assembly 90 is allowed to cool and is then finished. To finish the attached assembly the open end of the internal sock element 30 and the open end of the external sock element 32 are then joined together. This is done be either running the open

end of the attached assembly through a sewing machine 91 (shown) or another binding machine, such as a knitting machine.

Referring now to Fig. 5C, it can be seen from Step 7 that the attached assembly 90 is placed on a form 92. A reinforcement patch 28 is then affixed to the first end of the external sock element 32. The reinforcement patch 28 is a segment of tear resistant material that is coated on one side with an adhesive. The adhesive is preferably a heat activated adhesive. The reinforcement patch 28 is then placed against the attached assembly 90 and heated with an application iron.

A reinforcement patch 28 can be placed on only the external sock element 32. However, in a preferred embodiment a reinforcement patch 28 is placed against both the internal sock element 30 and the external sock element 32. To do this, the attached assembly 92 is removed from the blank 92, inverted and replaced on the blank 32, as is indicated by Step 8. The internal sock element 30 is now exposed. A second reinforcement patch is then applied to the internal sock element 30. The reinforcement patch on the interior sock element and the exterior sock element are concentrically oriented.

As is indicated by Step 9, a punch 94 is used to punch the aperture 26 through both reinforcement patches 28, the internal sock element, the external sock element and the elastomeric layer. The reinforcement patches 28 prevent the threads of the external sock element and the internal sock element from unraveling once the aperture 26 is created. The reinforcement patches 28 also help reinforce the elastomeric layer by stabilizing the edge of the elastomeric layer that is exposed to the aperture 28. At is last shown by Step 10, the finished liner sock 10 is removed from the manufacturing equipment and is ready for use.

The manufacturing process used to create the liner sock 50 illustrated in Fig. 3 is similar to that of liner sock 10 illustrated in Fig. 2. The step shown in Fig. 5A are used and the steps shown in Fig. 5C are shown. However, the steps shown in Fig. 5B are not used. A traditional sock is made and dipped in elastomeric material. However, no external sock element is used. Rather the reinforcement patches are applied directly to the interior sock element and the elastomeric material.

Referring To Fig. 6, an exemplary method of manufacturing the liner sock of Fig. 4 is illustrated.

The first step used to manufacture the liner sock 60 is to manufacture an initial sock element 62 in a traditional manner. The sock element 62 has a first end 95 that is closed and a second end 96 that is open, as is traditional for socks. In step 2, the sock element 62 is then dipped in a volume of molten elastomeric material 97. The depth of the dip, the temperature of the molten elastomeric material 97 and the number of dips determines the length and the thickness of the elastomeric layer 64 coating the sock element 62.

After a desired length and thickness of elastomeric layer 64 is obtained, the elastomeric layer 64 is allowed to cool or otherwise cure.

In Step 3, the sock assembly is temporarily inverted. So that the fabric is again exposed. The sock element 62 is again dipped in a volume of molten elastomeric material 97. The depth of the dip, the temperature of the molten elastomeric material and the number of dips determines the length and the thickness of the second elastomeric layer 64 coating the sock element 62. The second dipping of elastomeric material is then allowed to cure.

Finally, in Step 4, an aperture 66 is punched

through the first elastomeric layer, the sock element, and the second elastomeric layer. The presence of the elastomeric material on either side of the sock element prevents the thread of the sock element from unraveling once the aperture is created. The sock element also acts as a reinforcement to the elastomeric material, wherein the sock element stabilizes the exposed edges of the elastomeric material.

It will be understood that the embodiments of the present invention described and illustrated herein are merely exemplary and a person skilled in the art can make many variations to the embodiment shown without departing from the scope of the present invention. For example, many different types of fabrics and elastomeric materials can be used in the construction of the device. Additionally, the length and the width of the device can be altered depending upon whether or not the device is to be used above the knee, below the knee, above the elbow or below the elbow. All such variations, modifications and alternate embodiments are intended to be included within the scope of the present invention as defined by the appended claims.